

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of Claims

Claim 77 is requested to be cancelled without prejudice or disclaimer.

Claims 1, 61-67, 69, 79, and 80 are currently being amended. Support for these amendments can be found throughout the specification as-filed, including the original claims. Entry of these amendments respectfully requested, because these amendments simplify the issues for appeal and require no further searching.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims ??? are now pending.

II. Claim Rejections – 35 U.S.C. § 112, First Paragraph

Claims 1, 54, and 61-68 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description support. According to the Office Action, “[n]o persuasive support could be found in the specification or the originally filed claims for the expression ‘bearing at least one nitrogen group’ found in claims 1, 62-67 and 69.” Office Action at 4. Applicants respectfully traverse this ground of rejection.

“[T]o comply with the written description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession

of the subject matter later claimed by him.” *In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. 465, 467 (C.C.P.A. 1978) (citations omitted).

Here, the specification provides adequate support to demonstrate that Applicants had possession of the claimed invention at the time of filing. For example, page 11, lines 3-4, and page 17, lines 5-10 of the specification discuss “bearing at pendant nitrogen functionality” and gives examples of such groups. Specifically, structures (a)-(f) on page 17 of the specification are provided as examples of such groups. Moreover, the specification provides examples of specific compounds “bearing at pendant nitrogen functionality.” Given this support, one of skill in the art would clearly understand that Applicants were in possession of the claimed compounds “bearing at least one nitrogen group.” Applicants note that the written description requirement does not require *ipsis verbis* support, but instead, the specification must only “*reasonably convey* to persons skilled in the art that” Applicants had possession of the claimed invention at the time of filing. Applicants have clearly met that standard by providing both general disclosure and specific examples to support the phrase “bearing at least one nitrogen group.”

III. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1, 54, and 61-68 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. Each of the specific grounds of rejection is addressed below.

A. Claim 1 – Definition of “R”

Claims 1 and 63-65 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite, because “[i]n claim 1 [and 63-65], there are different definitions for the ‘R’ variable.”

While not acquiescing in the propriety of the rejection, Applicants have amended claims 1 and 63-65 to render the rejection moot. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

B. Claim 61 – Recited Species

Claim 61 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite, because “there are a number of specie listed which are not embraced by independent claim 1.”

While not acquiescing in the propriety of the rejection, Applicants have amended claim 61 to remove (viii), (xxxix), (xl), (xlii), (xliii), (xlv), and (xlv). However, Applicants have not removed compounds (xxv), (lxix), (ci), and (cii), because these compounds are embraced by claim 1. Specifically, these compounds are embraced by claim 1 when R¹ is defined as follows:

-C(O)R, -C(O)OR, or -CO-NRR', wherein R and R' are independently selected from the group consisting of hydrogen, aryl, heteroaryl, alkyl, and cycloalkyl, each optionally substituted with a heteroatom, and/or bearing at least one nitrogen group

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

C. Claims 62-66 – Improper Markush Language

Claims 62-66 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite because “of the use of improper Markush language found in the expression ‘an organic group that can be selected for example’.”

While not acquiescing in the propriety of the rejection, Applicants have amended claims 62-66 to render the rejection moot. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

D. Claim 63 – Halogen “I”

Claim 63 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for reciting “I” instead of “I.”

While not acquiescing in the propriety of the rejection, Applicants have amended claim 63 to correct this obvious typographical error. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

E. Claims 63-65 – R Substituent “Sulfonyl”

Claims 63-65 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite, because “there is a valence problem with the R substituent ‘sulfonyl’.”

While not acquiescing in the propriety of the rejection, Applicants have amended claims 63-65 to render the rejection moot. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

F. Claim 67 – Antecedent Basis

Claim 67 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite, because “the R⁴ variable does not represent hydrogen in claim 1.”

While not acquiescing in the propriety of the rejection, Applicants have amended claim 67 to render the rejection moot. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

G. Claim 69 – MPEP § 608.01(m)

Claim 69 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite, because the claim does not end in a period.

Applicants do not agree that the lack of a period renders the claim so unclear as to necessitate an indefiniteness rejection. Nonetheless, Applicants have amended claim 69 so that it ends in a period.

H. Claim 77 – Antecedent Basis

While not acquiescing in the propriety of the rejection, Applicants have canceled claim 77 thereby rendering moot any rejection of that claim. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

IV. Double Patenting

Claims 1 and 29-54 stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/523,018.” Office Action at 7-9.

Applicants note that the double patenting rejection is provisional. Thus, Applicants will address the rejection, if it ever becomes a non-provisional rejection.

V. Claim Rejections – 35 U.S.C. § 103

Claims 1, 54, 61, and 73-77 stand rejected under 35 U.S.C. § 103 as allegedly obvious over the following references, either alone or in any combination:

- (a) WO 00/33842 to Lago *et al.*;
- (b) U.S. Patent No. 3,467,666 to Dexter *et al.*;
- (c) U.S. Patent No. 3,201,409 to Spivack *et al.*;
- (d) U.S. Patent No. 6,291,514 to Illig *et al.*;
- (e) U.S. Pat. Appl. Pub. No. 2003/0158199 to Steiber *et al.*; and
- (f) U.S. Pat. Appl. Pub. No. 2001/0044545 to Dhanoa *et al.*

According to the Office Action, references (a)-(f) “each teach substituted phenylamino-2-thiazole compounds that are structurally similar to the instant claimed compounds.” Office Action at 11. The Office Action concludes that one of skill in the art would be motivated to make the specifically claimed compounds “from the expectation that structurally similar

compounds would possess similar activity (e.g., antagonizing the myt1 kinase receptor).” *Id.* at 12. Applicants respectfully traverse this ground of rejection.

There is not teaching or suggestion in the art to modify references (a)-(f) to arrive at the claimed invention. The Office Action contends that motivation stems “from the expectation that structurally similar compounds would possess similar activity (e.g., antagonizing the myt1 kinase receptor).” However, MYT1 kinase, which belongs to the Casein Kinase 1 family, has structure and properties vastly different from stem-cell factor receptors, such as c-kit. Given this differing structure and properties, one of skill in the art would have no motivation to modify the prior art compounds to discover compounds capable of selectively inhibiting c-kit. Indeed, a skilled artisan would have no reasonable expectation that an antagonist of one compound, MYT1 kinase, would be an inhibitor of another structurally different compound, c-kit. Applicants, however, surprisingly discovered that the presently claimed compounds are potent and selective inhibitors of c-kit (spec. at page 3, lines 7-12). This discovery is entirely unexpected based on the unrelated teachings of the cited references.

In addition, Applicants tested the claimed compounds and compounds disclosed by references (a)-(f) and determined that the claimed compound have superior and unexpected properties. Specifically, Applicants tested the compound on page 3, line 17 of Lago, the compound of example 13 of Dexter, the compound of example 19 of Spivack, compound 18 of Illig, compound 17 on page 7 and compound 35 on page 10 of Stieber, and compound 24 on page 6 of Dhanoa. None of these compounds, except for Lago’s compound, showed any c-kit inhibitory activity when tested against different forms of c-kit. Lago’s compound shows some activity, but Lago’s compounds did not discriminate between mutated c-kit and wild type c-kit. On the other hand, the many claimed compounds that were tested were *selective* in inhibiting c-kit. This selectivity and differential activity on the different forms of c-kit allows the use of wild-type c-kit inhibitors for treatment of conditions, such as inflammatory diseases and autoimmune diseases, and the use of mutated c-kit inhibitors for the treatment of conditions, such as the

aggressive forms of mastocytosis. The prior art does nothing to suggest this selective activity. Accordingly, the claimed compounds exhibit unexpected results.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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